the loop the two elements have the appearance of being one element. One such configuration may include configuring segment **21** as a horseshoe defining a cavity **23**, as shown in cross-section in FIG. **4**. Shaft **12** is then shaped to be received within cavity **23**. When the loop is collapsed, cavity **23** receives shaft **12** and the retention structure appears as one element instead of a separate segment **21** and shaft **12**. The actual circumference of the retention structure is therefore reduced making it physically easier to insertion and less traumatic on the patient. In addition, the thinner appearance would tend to be less intimidating to a patient.

The shaft and retention structure may be composed of a uniform material or may be composed of layers of material to confer the desired characteristics. When layered, the structure may include, for example, an inner layer of polyurethane surrounded by an outer layer of silicone or other combinations that confer desired characteristics. For example, the layered structures may be formed by inserting a polyurethane tube inside a silicone sleeve. The fit between the polyurethane tube and silicone sleeve is such that their contact minimizes slippage between the two. To develop sufficient contact, the silicone sleeve is typically soaked in a suitable solvent to swell the sleeve. The polyurethane tube is then inserted into the sleeve. As the solvent evaporates, the silicone sleeve contracts against the polyurethane tube. Typically, only the shaft is provided with such a silicon sleeve.

Using the above method of manufacture, the polyurethane tube holds the structure together while the silicone provides an appropriate surface for the sphincter to contract against. In addition, the retention structure may be integral with the shaft or formed independent of the shaft. When integral, device **10** may be formed from a single tube having its distal end wrapped around and secured to the tube to separately define the shaft and the retention structure. When formed independently, the retention structure may have a different shape and physical characteristics than the shaft.

The method of using a incontinence prevention device in accordance with the present invention is best understood with reference to FIGS. **5A**, **5B** and **5C**. The figures illustrate a method of linearizing a device **10**, as shown in FIG. **1**, for insertion into the urethra. FIG. **5A** shows an insertion tool **30** having a handle **32** attached to a stylet **34**. Handle **32** is not required but is typically provided for better control of the catheter during insertion. Stylet **34** is composed of a material, typically a metal wire, having sufficient rigidity to facilitate the insertion of the catheter into the urethra. Stylet **34** is typically sized to fit within lumen **18** of device **10**. In use, stylet **34** is inserted into shaft **12** through lumen **18** at the shaft's distal end, as shown in FIG. **5B**. Stylet **34** is advanced into shaft **12** through lumen **18**. Once the stylet's distal end reaches retention structure **14**, retention structure **14** assumes a conformation allowing insertion through the urethra, as shown in FIG. **5C**, due to forces conferred by stylet **34**. At this point, lubrication is typically applied to device **10**. If the device is hydrogel coated, the device is lubricated simply by moistening the material. Alternatively, a water-soluble lubricant, like K-Y Jelly, or other suitable lubricant may be applied to the catheter's surface. In the embodiment shown, stylet **34** is typically advanced until retention structure **14** collapses in on itself due to the rigidity of the stylet and the tension exerted between the distal tip of stylet **30** and the point **36** where the loop attaches to shaft **12**. Thus, insertion of the stylet renders urethral catheter **14** substantially rectilinear so as to allow insertion into a urethra. Retention structure **14** is then inserted into the urethra. Once retention structure **14** of the incontinence prevention device **10** is positioned within the urinary bladder, the stylet is removed allowing retention structure **14** to resume its original configuration. The proximal end of device **10** is then manipulated, if necessary, to properly orient non-concentrically configured retention structure **14** adjacent to the bladder neck within the patient. The orientation of retention structure **14** may be reflected by reference to orientation marking **38** on shaft **12**. Thus, for example, when orientation marking **38** is oriented ventrally, retention structure **14** is properly oriented within the patient's bladder.

What is claimed is:

1. An incontinence prevention device comprising:

(a) a flexible shaft member sized to fit within the urethra of a female; and

(b) a retention structure formed on a distal end of the flexible shaft, the retention structure forming a perimeter of a closed loop defining a plane that is generally lateral [perpendicular] to a longitudinal axis of the flexible shaft when the retention structure is unrestrained, said longitudinal axis being offset from a center of the closed loop so as to pass through the perimeter of the closed loop.

2. An apparatus, as in claim **1**, further comprising a lumen configured to receive a stylet, wherein the lumen is coextensive with the shaft and substantially coextensive with the retention structure.

3. An apparatus, as in claim **1**, further comprising a hydrogel coating disposed on an outer surface of the catheter.

4. An apparatus, as in claim **1**, wherein the shaft includes an orientation marking at a proximal end of the shaft.

5. An apparatus, as in claim **1**, wherein a proximal end of the shaft includes a beveled edge.

6. An apparatus, as in claim **1**, wherein the retention structure further includes a protuberance projecting from the retention structure.

7. An apparatus, as in claim **6**, wherein the protuberance projects from a midpoint of the closed loop.

8. An apparatus, as in claim **6**, further comprising a lumen coextensive with the shaft and protuberance configured to receive a stylet.

9. An apparatus, as in claim **8**, wherein the lumen extends through a distal end of the protuberance.

10. An apparatus, as in claim **8**, wherein the lumen extends to a point proximal to a distal end of the protuberance.

11. An apparatus, as in claim **6**, wherein a segment of the retention structure defines a cavity to receive a portion of the retention structure.

12. A method treating incontinence, comprising:

providing an apparatus including a shaft and a retention structure, wherein the retention structure forms a perimeter of a closed loop defining a plane that is generally [perpendicular] lateral to a longitudinal axis of the shaft and the longitudinal axis of the shaft is offset from a center of the closed loop and passes through the perimeter of the closed loop when the retention structure is unrestrained;

rendering the retention structure substantially rectilinear;

inserting the rectilinear retention structure through a urethra into a bladder;

reforming the retention structure into the closed loop; and

positioning the retention structure adjacent the neck of the bladder with the retention structure in a predetermined orientation.

13. The method, as in claim **12**, wherein the apparatus further comprises a lumen configured to receive a stylet,

wherein the lumen is coextensive with the shaft and substantially coextensive with the retention structure.

14. The method, as in claim **13**, (**12**, further comprising providing a stylet and) wherein the stylet is inserted into the lumen in the apparatus to render the retention structure substantially rectilinear.

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